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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,985	09/05/2003	David J. Kyle	8717.0010	5651

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/654,985

Applicant(s)

KYLE, DAVID J.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-119 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-31, 33, 34, 36, 37, 39, 40, 52-56, 58-61, 63, 64, 98, 103-105 and 107-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1-14-04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Claims 1-119 are pending.
2. Applicant's election of Group V, and to inventions of Group A (wherein the biomass comprises a peptide), and wherein the peptide is a bactericidal acidic peptide, and to embodiments wherein the composition comprises a fungal (or yeast) biomass and a peptide in the reply filed on April 19, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that the claims drawn to yeasts represent a subspecies of fungus. The restriction between Groups V and III is therefore withdrawn.
3. Claims 1-27, 32, 35, 38, 41-51, 57, 62, 65-97, 99-102, and 106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species or inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 19, 2005.
4. Currently, claims 28-31, 33, 34, 36, 37, 39, 40, 52-56, 58-61, 63, 64, 98, 103-105, and 107-109 are pending and under consideration.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on January 14, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

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6. The following reference is in a foreign language accompanied by an English abstract.

Due to this, the reference has been examined only to the extent of the disclosure in the abstract.

WO 02/15721.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 28-31, 33, 34, 36, 39, 40, 52-56, 58-60, 64, 98, 103-105, and 109 are rejected under 35 U.S.C. 103(a) and obvious over the teachings of Duke et al. (U.S. 5,830,463- of record in the January 2004 IDS). These claims are drawn to compositions comprising a yeast/fungus and a peptide- particularly an antibiotic peptide. The claims further provide for limitations wherein the yeast/fungus is a *Saccharomyces* strain, and wherein the composition is a feed or feed additive.

Duke teaches the use of recombinant yeast as delivery vehicles for therapeutic compounds. Abstract, and columns 4-5. Among the yeasts that are identified as useful for the described purposes, the reference identifies *Saccharomyces* yeasts. Column 6, lines 50-64. The reference teaches that the yeast may be designed to produce antibiotics. Col. 10, esp., lines 42-43; and column 15 lines 28-37. Further, the reference teaches that the yeasts may be administered to animals orally, including in food or beverage formulations (col. 19, lines 6-11), and that they may be administered to any suitable animals (col. 20, lines 44-50). Duke

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additionally teaches that the peptides produced by the yeast may inhibit infection by (thereby inhibiting the growth or replication of) pathogens including *Vibrio* pathogens. Column 7, lines 51-67, esp., line 67. Because the reference teaches that the yeast delivery vehicles described therein may be used to produce antibiotics, and formulated into food compositions, those in the art would have had a reasonable expectation of success in making the suggested yeast compositions. The teachings of the reference therefore render the claimed inventions obvious.

9. Claims 28-31, 37, 39, 40, 52-56, 64, 98, 104, 105, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rentier-Delrue et al. (WO 90/07578) in view of Tusé et al. (Crit Rev Food Sci Nutr 19: 273-325)(both references of record in the IDS of Jan 2004). These claims read on food compositions or supplements comprising recombinant yeasts which produce therapeutic peptides or proteins.

Rentier-Delrue teaches the production of therapeutic fish proteins in yeast cells. Page 7. However, while the reference teaches the production of the proteins in yeast cells, and the administration of the proteins as part of a food, the reference does not teach that the yeast cell may also be included in such compositions.

Tusé provides teachings relating to the use of microbial cells as a source of nutritional and other proteins. The reference indicates that such microbial cells, including yeast cells, may be used in animal feeds and animal feed supplements. Pages 273 and 274-75. Further, the reference indicates that such yeast cells would be practically available as a feed for various animals, including fish. Page 297. Finally, the reference also teaches that such microorganisms could be genetically modified “to improve the protein content” of the cells, including for the

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expression of foreign (to the microorganism) proteins. Pages 314-316. In view of these teachings indicating that yeast cells, including those with genetic modifications to produce foreign proteins, it would have been obvious to those in the art that the recombinant yeast cells used by Rentier-Delrue to produce fish proteins could themselves be included in the feeds and supplements used to deliver the produced proteins.

Those in the art would have been motivated to combine the teachings because the combination would have avoided the need for the additional steps of isolating the produced proteins, and because the Tusé reference indicates that the yeast cells provide additional nutritive content. In view of the suggestion by Tusé that such recombinant cells would be useful in feeds and supplements, those in the art would have had a reasonable expectation of success in the combination. The combined teachings of these references therefore render the claimed compositions obvious.

10. Claims 63 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusé, further in view of the teachings of Knutzon et al. (U.S. 5,968,809) and Duke (described above), and in light of the teachings of Mackenzie et al. (Appl Environ Microbiol 66: 4655-61). These claims read on the compositions described above, except that they require that the fungus is a species of *Mortierella*.

The teachings of Tusé have been described in part above. As indicated above, the reference teaches the use of microorganisms in feed compositions, and suggests the genetic modification of the compositions for additional proteins. Among the microorganisms suggested for use by the reference are filamentous fungi and yeasts. Thus, the reference indicates that both

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such cell may be used in animal feeds. However, the reference does not specifically teach the modification of the fungi to produce an antibiotic peptide or protein.

Knutson teaches that the recombinant production of certain proteins in host cells. Among the host cells identified as useful in the production of such proteins are fungal cells such as filamentous fungi and *Mortierella* (column 4 line 48 to column 5 line 2, and cols 15-16). See also, Mackenzie, page 4655 teaching that *Mortierella* is also a filamentous fungus, and the transformation of that fungus to produce heterologous proteins (histones). The combined teachings of these references teach that *Mortierella* fungus can be used as a feed or feed supplement, and that the fungus may be used for the production of heterologous proteins. However, the references do not, without more suggest the modification of the fungus to produce a therapeutic protein, and to include such modified fungi into feed compositions.

However, as was indicated above, the Tusé reference teaches that the fungus shares with yeasts the ability to be included in foods and food supplements. Additionally, the Duke reference teaches that yeasts may be modified to express therapeutic proteins, including antibiotics, and teaches that the yeasts producing the protein, and thus the protein, may be administered to an animal by the inclusion of the yeast in food compositions. The combined teachings of Tusé, Knutson, and Mackenzie demonstrate that the *Mortierella* fungus is functionally equivalent to yeasts in its ability to produce foreign proteins, and its utility as an additive in food compositions. From these teachings, it would have been obvious to those in the art that the fungus could also be substituted for the yeast cells described in the Duke reference.

Those in the art would have been motivated to do so based on the teachings in the art that *Mortierella* cells are suitable for both the functions required by the yeast cells of Duke. See e.g.

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MPEP 2144.06 (indicating that no express suggestion to substitute one component with an equivalent is necessary so long as the equivalency is recognized in the art). As indicated above, the art teaches that, for each of the functions required in the present composition, the *Mortierella* fungus was known to be functionally equivalent to the yeast cells of Duke. It would therefore have been obvious to those in the art to substitute one with the other.

Those in the art would have had a reasonable expectation of success in such a combination based on the teachings of Tusé suggesting the use of the filamentous fungus (of which *Mortierella* is a member) as a food additive and suggesting the modification of the cells to express additional proteins, and the teachings of the other references demonstrating that the fungus is a suitable host cell for heterologous protein expression. The combined teachings of these references therefore render the claimed inventions obvious.

11. Claims 37, 61, and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke as applied to claims 28-31, 33, 36, 39, 40, 52-56, 58, 60, 64, 98, 103-105, and 109 above, and further in view of Hamill et al. (U.S. RE 32,333). These claims read on the previously described compositions wherein the antibiotic is an acidic protein. The teachings of Duke have been described above. While the reference teaches the use of yeast (a type of fungus) to produce antibiotics, the reference does not specifically teach the production of acidic proteins. However, Hamill indicates that the acidic proteins were a known category of antibiotics. See e.g., column 1, lines 23-40. Because Duke teaches that the yeasts disclosed therein may be altered to produce antibiotics, and because the acidic proteins of Hamill were a known group of antibiotic peptides, it would have been obvious to those in the art to use the yeasts of Duke to produce the antibiotic

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peptides of Hamill. Those in the art would have had a reasonable expectation of success based on the teachings in Duke that the yeasts may be used to produce antibiotics, as well as other types of proteins and compounds. Thus, the limitations of the indicated claims would have been obvious to those in the art.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 28-31, 33, 34, 36, 37, 40, 52-56, 58-61, 64, 98, 103-105, 107, and 109 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 10 of copending Application No. 10/683,361. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application describe a species of the presently claimed genus, and because the additional limitations of the present claims (i.e. the use of yeasts or fungi in the biomass) as described as embodiments of the inventions claimed by the copending application. See, pages 1, 2, and 13 of the copending application. Thus, the claims of the copending application represent an obvious variation of the presently claimed generic inventions.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 39, 63, 108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 10 of copending Application No. 10/683,361, further in view of either Duke, or of the teachings of Tusé, Knutson, and Mackenzie. Claim 39 describes the claimed invention wherein the host cell is a *Saccharomyces* yeast. Claims 63 and 108 describe embodiments wherein the cell is a *Mortierella* filamentous fungi. The teachings of the copending application have been described above. As indicated above, the reference teaches the claimed embodiments wherein the host cell is a yeast or a fungus. However, the reference does not specifically teach the use of either *Saccharomyces* or *Mortierella* cells.

The teachings of Duke, and of Tusé, Knutson, and Mackenzie have been described above. As indicated above, Duke teaches the use of yeast cells in a similar manner to that claimed by the copending application. As indicated above, the combined teachings of Tusé, Knutson, and Mackenzie indicate that *Mortierella* cells have characteristics that would make them suitable for use in the method described by the copending application (i.e. they may be used for expression of heterologous proteins, and are suitable for inclusion in food compositions). It would therefore have been obvious to those in the art to substitute either of these types of cells for the yeasts or fungi suggested in the copending application. The claims of the present application therefore represent an obvious variation on the methods suggested by the copending application.

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This is a provisional obviousness-type double patenting rejection.

15. The above rejections are, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804 II(B)(1):

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

Conclusion

16. No claims are allowed.

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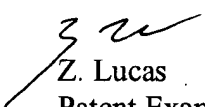
17. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

Kitao et al., U.S. 5,281,596. This reference teaches antimicrobial compounds effective for the treatment of infections in fish. Cols. 1-2. The reference additionally teaches that the compounds may be included in feed compositions for administration. Col. 2, lines 53-59. However, the reference does not teach the use of recombinant fungi or yeasts for the production of compounds, or the inclusion of yeast or fungal biomasses in the compositions.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 6/24/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-27,32,35,38,41-51,57,62,65-97,99-102,106 and 110-119.